

The opinion in support of the decision being entered today  
is not binding precedent of the Board.

23  
Paper No. 115

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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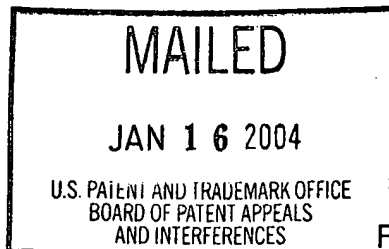
RONALD M. EVANS, DAVID J. MANGELSDORF, RICHARD A. HEYMAN,  
MARCUS F. BOEHM, GREGOR EICHELE, AND CHRISTINA THALLER

Junior Party<sup>1</sup>

v.

WERNER BOLLAG, JOSEPH FRANCIS GRIPPO, AND ARTHUR LEVIN

Senior Party,<sup>2</sup>



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Patent Interference No. 103,842

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FINAL HEARING: September 15, 2003

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Before: CAROFF, HANLON, and LORIN, Administrative Patent Judges.

LORIN, Administrative Patent Judge.

This is a Final Decision in Interference 103,842 resolving the issues raised at final hearing, 37 CFR § 1.658.

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<sup>1</sup> Application 08/244,857, filed 12/18/92. Assignors to The Salk Institute for Biological Studies, Baylor College of Medicine, and Ligand Pharmaceuticals, Inc.

<sup>2</sup> Application 08/201,493, filed 02/24/94, now U.S. Patent No. 5,428,071 issued 06/27/95. Assignors to Hoffmann-La Roche Inc.

The interference involves:

- Evans et al. [Evans] Application 08/244,857 ['857], filed December 18, 1992.
- Bollag et al. [Bollag] Application 08/201,493, filed 02/24/94, now U.S. Patent No. 5,428,071 ['071], granted June 27, 1995.

Counts 1 and 2 define the interfering subject matter, 37 CFR §1.601(f):

COUNT 1

A method for treating patients having premalignant or precancerous epithelial lesions to retard the progression of these lesions into carcinomas comprising administering to said patient a composition containing a compound selected from the group consisting of 9-cis-retinoic acid, its pharmaceutically acceptable salts, and its pharmaceutically acceptable hydrolyzable esters said compound being administered in an amount effective to treat said lesions.

The parties' claims which are designated to correspond to Count 1 are (see paper no. 1):

- Bollag '071 patent: claims 1-6.
- Evans '857 application: claim 51.

The parties' claims which are designated not to correspond to Count 1 are (see paper no. 1):

- Bollag '071 patent: claims 7-14.
- Evans '857 application: claims 36-40, 52.

COUNT 2

A method for treating tumors of epithelial origin in patients to retard the development of these tumors comprising administering to said patient a composition containing a compound selected from the group consisting of 9-cis-retinoic acid, its pharmaceutically acceptable salts, and its pharmaceutically acceptable hydrolyzable esters, said compound being administered in an amount effective to retard the development of said tumors.

The parties' claims which are designated to correspond to Count 2 are (see paper no. 1):

- Bollag's '071 patent: claims 7-13; and,
- Evans's '857 application: claims 36, 38-40, 52.

The parties' claims which are designated not to correspond to Count 2 are (see paper no. 1):

- Bollag's '071 patent: claims 1-6 and 14; and,
- Evans's '857 application: claims 37 and 51.

Bollag has been accorded benefit of the January 22, 1992 filing date of its earlier-filed application 07/823,741 ['741], now abandoned. See Paper No. 1.

Evans has not been accorded benefit of an earlier filing date. The Notice declaring the interference (Paper No. 1) indicates that Evans was accorded the December 18, 1991 filing date of Evans earlier-filed Application 07/809,980 ['980], but the Administrative Patent Judges [APJs] granted Bollag Preliminary Motion 1 filed under 37 CFR § 1.633(g) attacking this benefit (Paper No. 13). See Decision on Motions, Paper No. 54, p. 23. The APJs denied Evans' subsequent request filed pursuant to 37 CFR § 1.640(c) (Paper No. 59) for reconsideration of the granting of Bollag Preliminary Motion 1. See Decision on Request For Reconsideration, Paper No. 64.

By virtue of being accorded the benefit of an earlier filing date (January 22, 1992) with respect to all the counts, Bollag is the senior party in this interference. 37 CFR §§ 1.657 and 1.601(m).

The following papers have been submitted:

- "Junior Party Evans' Opening Brief For Final Hearing," Paper No. 106 [hereinafter EB];
  - Evans Record, Paper No. 101 [hereinafter ER];
  - Evans Exhibits, Paper No. 102 [hereinafter EX];
- "Senior Party Bollag's Brief For Final Hearing," Paper No. 108 [hereinafter BB];
  - Bollag Record, Paper No. 99 [hereinafter BR];

- Bollag Exhibits, Paper No. 100 [hereinafter BX];
- Bollag Motion to Strike, Paper No. 107;
- Evans Opposition to Bollag Motion to Strike, Paper No. 110;
- "Junior Party Evans' Reply Brief For Final Hearing," Paper No. 109 [hereinafter ERB]; and,
- Bollag Reply to Evans Opposition to Bollag Motion to Strike, Paper No. 111.

No issue of no interference-in-fact was raised at final hearing.

### DISCUSSION

#### Inventorship

Bollag (BB 58-59) raises a threshold question of patentability as to Evans' claimed invention under 35 U.S.C. § 102(f) in view of an alleged admission on the part of Evans that the inventorship indicated on Evans' involved application is incorrect, coupled with the fact that Evans has failed to correct the error. Bollag, citing Schultze v. Green, 136 F.3d 786, 790, 45 USPQ2d 1770, 1773 (Fed. Cir. 1998) and Louis v. Okada, 2002 WL 31358220 (Bd. Pat. App. & Int. 2002), argues that prima facie evidence of unpatentability under 35 U.S.C. § 102(f) now exists.

The facts are as follows:

- During the preliminary motions period, Evans (Evans Motion 1) moved to correct the inventorship of its involved '857 application, stating the following:

Pursuant to 37 CFR § 1.634 Senior Party Evans et al. hereby moves to correct the inventorship of its application involved in this interference, namely U.S. Patent Application No. 08/244,857 ... pursuant to 37 CFR § 1.48(b).

During the prosecution of the '857 Application, cancellation and amendment of claims has resulted in the invention of Marcus Boehm no longer being claimed. ...

Paper No. 22, p. 1.

- Bollag (Paper No. 29) opposed the motion on the grounds that Evans failed to submit evidence 1) of an error in inventorship which needed to be corrected and 2) that Evans diligently sought to correct the alleged error. In addition to the

opposition, Bollag requested that it be permitted to obtain from Evans testimony of various individuals to support its opposition.

- Evans (Paper No. 48) replied that its motion provides the necessary evidence and reflects its diligence in filing the motion in compliance with the rules. Evans also opposed Bollag's request for additional testimony on the matter.
- Bollag (Paper No. 49) further replied that Evans did not comply with rules 634 and 636 and, because of Evans' failure to provide evidence on the matters of error and diligence, additional testimony from party Evans on the matter was necessary.
- The Decision on Motions (Paper No. 54, p. 44) deferred decision on Evans Motion 1 to correct inventorship to final hearing.
- During the testimony period and in compliance with 37 CFR § 1.640(b), Evans (Paper No. 68) identified issues it wanted reviewed at final hearing. Among the issues it wanted reviewed were those related to Evans' Motion 1. Evans stated the following:

2. All issues relating to Evans Motion 1 to correct the inventorship of Party Evans' U.S. Application No. 08/244,857 ("the '857 application") pursuant to 37 CFR § 1.48(b), including without limitation, that Marcus F. Boehm should be removed as a named inventor in the '857 application.

- Evans' Opening Brief (Paper No. 106, pp. 7-8) for final hearing does not include issues related to Evans' Motion 1 among the issues presented for decision.
- Bollag's Brief (Paper No. 108, pp. 58-59) for final hearing notes that "Evans conspicuously does not request the Board to decide [Evans' Motion 1]." Bollag contends that, in view of 37 CFR § 1.640(b)<sup>3</sup>, Evans has "irretrievably surrendered its right to seek correction of the admitted error in inventorship." Bollag then argues that the failure to make the correction in inventorship should lead to a decision of adverse judgment against Evans on the grounds that an admitted error in inventorship, which has not been corrected, means all the Evans claims in interference are unpatentable under 35 U.S.C. §102(f).
- Evans' Reply Brief (Paper No. 109, pp. 83-84) argues
  - that new evidence, that is evidence not available until after Evans Motion 1 was filed - specifically speaking, the declaration of Marcus Boehm executed

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<sup>3</sup> "A matter raised by a party in support of or in opposition to a motion that is deferred to final hearing will not be entitled to consideration at final hearing unless the matter is raised in the party's brief at final hearing."

on December 4, 2002 (Evans Exhibit 1093) – shows that Marcus Boehm is indeed an inventor. Evans argues that, in view of the new evidence, “Party Evans has abandoned the issue it raised in its November 3, 1997 Motion to Correct Inventorship.” Evans states that “Party Evans decided not to raise this issue for decision at final hearing since this evidence of record reveals that Evans’ ‘857 patent application presently names the correct inventors.”

- that Bollag opposed Evans Motion 1 on the grounds that Evans failed to present evidence establishing an error in inventorship needing correction and thus “cannot now argue based on the record before it that the Evans’ ‘857 application is somehow unpatentable under 35 U.S.C. 102(f).”

We have carefully considered the facts set forth above and reviewed the court decisions cited by Bollag in support of its position. We are of the opinion that the decisions do not lead to a per se holding of unpatentability under 35 U.S.C. § 102(f) of Evans’ claims under the circumstances in this case.

Bollag neither filed a motion under 37 CFR § 1.633(a) for judgment on the grounds that Evans claims are unpatentable under 35 U.S.C. § 102(f) nor raised a question of unpatentability in its opposition to Evans’ Motion to Correct Inventorship. The question of unpatentability is raised for the first time in Bollag’s brief. Bollag is of the present view that the record supports a question of the patentability of Evans’ claims under 35 U.S.C. § 102(f). However, the record on the matter of inventorship of Evans’ invention has not changed since this interference was declared. Bollag could have raised a question of patentability through a motion filed under 37 CFR § 1.633(a) during the preliminary motions period but Bollag appears to have elected not to do so. Furthermore, Bollag has not shown good cause why this question of patentability was

not earlier raised by a timely filed motion. Consistent with Rule 655(b)<sup>4</sup>, the question of unpatentability that Bollag now raises in its brief will not be considered.

Nevertheless, we make the following points in order to fully address the issues raised by Bollag in its brief.

First, it should be noted that the Decision on Motions (Paper No. 54, p. 44) indicates that the Board deferred decision of Evans' motion to correct inventorship. As Bollag has stated, 37 CFR § 1.640(b) applies in this situation. That is to say, matters raised by Evans in its motion to correct inventorship would not be entitled to consideration at Final Hearing if not raised in its brief. In fact, Evans' brief does not include a request that the Board revisit its motion to correct inventorship and reach a decision on that matter.

Second, Bollag would have the panel consider Evans' Motion to correct inventorship as an admission on the part of Evans that the inventorship now indicated on the application is incorrect. According to Bollag where a party admits to an error in inventorship and the error has not been corrected, a question of the patentability under 35 U.S.C. § 102(f) automatically attaches to that party's claims. In support thereof, Bollag cites *Schultze v. Green*, 136 F.3d 786, 790, 45 USPQ2d 1770, 1773 (Fed. Cir. 1998) and *Louis v. Okada*, 2002 WL 31358220 (Bd. Pat. App. & Int. 2002).

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<sup>4</sup> "A party shall not be entitled to raise for consideration at final hearing any matter which properly could have been raised by a motion under § 1.633 or § 1.634 unless the matter was properly raised in a motion that was timely filed by a party under § 1.633 or § 1.634 and the motion was denied or deferred to final hearing, the matter was properly raised by the party in a timely filed opposition to a motion under § 1.633 or § 1.634 and the motion was granted over the opposition or deferred to final hearing, or the party shows good cause why the issue was not properly raised by a timely filed motion or opposition." 37 CFR § 1.655(b).

We have reviewed the Schultze and Louis decisions. Neither decision supports a per se rule that a party's position that an incorrect inventorship exists that is raised in its motion but not raised for consideration by the party at final hearing renders the party's claims in interference automatically unpatentable under 35 U.S.C. § 102(f) absent the opposing party raising the issue in a motion or opposition to the party's motion to correct inventorship. In Louis, unlike the present case, inventorship was a central issue. In fact, a motion to correct inventorship was filed as a means of overcoming an opposing party's motion for judgment. There the facts strongly supported the conclusion that the inventorship was indeed incorrect. Here, Evans contends that it did not raise its motion to correct inventorship at final hearing because it has determined that the inventorship is in fact correct. Unlike in Louis, the present facts raise some doubt as to whether the indicated inventorship is in fact incorrect. In Schultze, unlike here, the party's motion to correct inventorship was dismissed and the opposing party subsequently filed a motion for judgment that subject matter corresponding to the count was unpatentable to the party under 35 U.S.C. § 102(f). Here no motion for judgment on the grounds of unpatentability under 35 U.S.C. § 102(f) has been filed. In fact, in its opposition to Evans' motion to correct inventorship, Bollag took the position that Evans did not establish an error in inventorship. Belatedly, Bollag now takes the view that Evans has admitted an error in inventorship; to put it another way, Bollag has reversed course and now takes the view that an error in inventorship has been established on the part of Evans by way of an alleged "admission." This situation is unlike that of Schultze where the issue of unpatentability under 35 U.S.C. § 102(f) was fairly raised



by the opposing party by way of a motion for judgment.

Priority

There is no dispute that Bollag, the senior party, is entitled to benefit of the January 22, 1992 filing date of its earlier-filed '741 application for priority purposes as to the subject matter of Counts 1 and 2. Furthermore, Bollag makes no case for priority other than to rely on the January 22, 1992 filing date of its earlier-filed '741 application as evidence of a constructive reduction to practice of the subject matter of Counts 1 and 2. Accordingly, we find that senior party Bollag's priority date as to both counts is January 22, 1992.

Evans, as the junior party, has the burden of establishing priority by a preponderance of the evidence. 37 CFR § 1.657(b). Bosies v. Benedict, 27 F.3d 539, 30 USPQ2d 1862 (Fed. Cir. 1994). Evans must establish that it reduced to practice, either actual or constructive, the inventions of Counts 1 and 2 before senior party Bollag's priority date of January 22, 1992, or that it first conceived the inventions of both counts prior to that date and, from a time prior to Bollag entering the field, proceeded with diligence toward a reduction to practice, either actual or constructive. Haskell v. Colebourne, 671 F.3d 1362, 1365, 213 USPQ 192, 194 (CCPA 1982).

Evans puts forward three alternative legal arguments:

- I. Evans was first to constructively reduce to practice the invention of the counts<sup>5</sup>;
- II. Evans was first to actually reduce to practice the invention of the counts<sup>6</sup>; and,
- III. Evans conceived of the invention of the counts prior to January 22, 1992, and proceeded with diligence toward a constructive reduction to practice<sup>7</sup>.

If the preponderance of the evidence supports any one of these three arguments, Evans will have met its burden of establishing priority.

I. Evans 1<sup>st</sup> Legal Argument For Priority: It Was The First To Constructively Reduce To Practice The Invention Of The Counts.

Evans argues that it was first to constructively reduce the invention of Counts 1 and 2 to practice. As evidence of an earlier constructive reduction to practice, Evans points to its earlier-filed '980 application, which was filed on December 18, 1991, more than a year prior to Bollag's January 22, 1992 priority date.

The record indicates that the APJs below granted Bollag Preliminary Motion 1 filed under 37 CFR § 1.633(g) (Preliminary Motion 1, Paper No. 13) attacking the

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<sup>5</sup> "[The July 27, 2001 Decision on Motions] misapprehended or overlooked several important facts and applied the wrong legal standard [and therefore] it should be reversed and Party Evans should be afforded the benefit of priority of the December 18, 1991 filing date of the '980 application. Doing so would entitle Party Evans to a judgment on priority as to the subject matter of the two counts in this interference because Party Bollag is limited to a January 22, 1992 priority date" (EB 108).

<sup>6</sup> "Evans can establish an actual reduction to practice of a method of administering an effective amount of 9cisRA [9-cis-retinoic acid] to a patient for the purpose of treating precancerous epithelial lesions or tumors of epithelial origin ... between December 9<sup>th</sup> and 12<sup>th</sup>, 1991 and then again between January 17<sup>th</sup> and 20<sup>th</sup>, 1992, all before the January 22, 1992 Bollag priority date" (EB 75).

<sup>7</sup> "Evans can establish a conception of the subject matter of the counts prior to Party Bollag's January 22, 1992 priority date [per, for example, the December 18, 1991 filing of Evans' '980 application]," (EB 52) and "Evans can further establish diligence towards a reduction to practice of a method of administering epithelial lesions or tumors of epithelial origin beginning just prior to January 22, 1992 and continuing through until Evans' subsequent constructive reduction to practice, the December 18, 1992 filing of Evans' involved '857 application" (EB 86).

benefit of the December 18, 1991 filing date of Evans' earlier-filed '980 application accorded Evans in the Notice declaring the interference. See Decision on Motions, Paper No. 54, pp. 7-23. In granting Bollag Motion 1, the APJs found that Bollag had successfully met its burden of showing that Evans was not entitled to the benefit, for priority purposes, of the December 18, 1991 filing date of Evans' earlier-filed '980 application. Accordingly, Evans' earlier-filed '980 application was held not to be a constructive reduction to practice of the subject matter of the counts.

Evans is challenging the APJs' holding in the Decision on Motions that Evans' earlier-filed '980 application was not a constructive reduction to practice of the subject matter of the counts. By advancing the argument that Evans' '980 application, filed on December 18, 1991, is a constructive reduction to practice of the invention of Counts 1 and 2, Evans is requesting that the panel overturn the APJs' decision granting Bollag Motion 1 and find instead that Evans is indeed entitled to the benefit of its earlier-filed '980 application for priority purposes for the subject matter of the counts. Concurrently, we are being asked to reverse the APJs' decision (Decision on Request For Reconsideration, Paper No. 64) denying Evans' prior request for reconsideration (Paper No. 59) of the granting of Bollag Preliminary Motion 1.

Evans' argument is, however, subject to Bollag's Motion to Strike (Paper No. 107). Accordingly, we decide Bollag's Motion to Strike before addressing the merits of Evans' argument.

Bollag Motion to Strike

Bollag has filed a "Motion to Strike Portions of Evans' Brief Directed to Evidence and Arguments Not Raised In Connection With Preliminary Motion For Which Review Is Sought," Paper No. 107. Specifically, Bollag (Paper No. 107, pp. 5-6) seeks to strike the following evidence and arguments raised in Evans' Brief (EB 108-128):

- (1.) Declaration of Ronald Evans (cited, for example, at EB 122, 124, and 126);
- (2.) Declaration of David Mängelsdorf (cited, for example, at EB 122, 124 and 126);
- (3.) Declaration of Richard Heyman (cited, for example, at EB 122, 124 and 126);
- (4.) Declaration of Jonathan Kurie (cited, for example, at EB 122, 124 and 126);
- (5.) the point that epithelial is one of four subgenera (see EB 112-15 and 120);
- (6.) the point made in reference to the Examples in Evans' '980 application (see EB 121-22); and
- (7.) the point made with regard to Figure 3 of the specification in Evans' '980 application (see EB 121-26).

There is no dispute that Evans' argument relies, in part, on the evidence and points listed above. The issue is whether this evidence and these points should be considered in deciding the merits of Evans' argument. We find that these are new evidence/arguments in violation of 37 CFR § 1.655(b) and therefore we will not consider them in reaching a decision on the matter.

We are of the view that all of the evidence and points listed supra which Evans has raised in support of its argument that it was first to constructively reduce the invention of Counts 1 and 2 to practice are new arguments in violation of 37 CFR § 1.655(b).

According to 37 CFR § 1.655(b), Evans can rely on the evidence and points listed supra only if 1) they were submitted with the opposition to Bollag Motion 1, or 2) Evans has shown "good cause why the issue was not properly raised by a timely filed

motion or opposition," . We have reviewed the opposition (Paper No. 31) to Bollag Motion 1 but we find no mention of the evidence and points listed supra. We are aware that a number of the points listed supra [i.e., points (5.)-(7.)] were raised in Evans' "Request for Reconsideration," Paper No. 59, but the "Decision on Request for Reconsideration," Paper No. 64 [see p. 6, 16 and 17 for points (5.)-(7.), respectively] clearly indicates that these points were not raised in the opposition. Notwithstanding that the APJs nevertheless addressed these newly raised points in the "Decision on Request for Reconsideration," apparently in an attempt to cover all the arguments raised in Evans' "Request for Reconsideration", we decline to make comments about issues raised in contravention of the rules, especially when doing so, as here, could potentially place the Board in a position of acting as an advocate for Evans to Bollag's detriment.

"Pursuant to 37 CFR § [1.655(b)], a party is not entitled to raise for consideration at final hearing a matter which could have been properly raised by motion unless the party shows good cause why the issue was not timely raised by motion," Grove v. Johnson, 22 USPQ2d 1044, 1046 (Bd. Pat. App. & Int. 1991). The matters listed supra were not properly raised in Evans' opposition to Bollag Motion 1 and no good cause has been shown why these matters were not timely raised. Accordingly, we will not consider these matters in deciding Evans' argument that it was first to constructively reduce the invention of Counts 1 and 2 to practice set forth in its Brief.

Bollag's Motion to Strike is GRANTED.

Regarding Evans' opposition to Bollag's Motion to Strike, Paper No. 110, it is belated by two days without explanation. The "Second Order Setting Testimony And Briefing Times," Paper No. 66, pp. 14-15, specifically states that an opponent's opposition to a moving party's motion to suppress evidence (i.e., Bollag's Motion to Strike) "is due with the opponent's next scheduled brief," which in the case of Evans was the close of business, Tuesday, September 2, 2003. The setting of that date – September 2, 2003 – as the date by which Evans had to submit its Reply Brief can be found emphasized on page 2 of the "Decision on Bollag's Motion for Extension of Time and On Evans' Rule 635/616 Motion [&] Third Order Setting Testimony, Briefing Times," Paper No. 94. The record appears to be clear and unambiguous on this matter. Evans' Reply Brief was properly submitted on September 2, 2003 but the Certificate of Mailing attached to Evans' opposition states that the opposition was mailed on September 4, 2003, two days later, and therefore, in view of the indication in the "Second Order Setting Testimony And Briefing Times," Paper No. 66, pp. 14-15, it is untimely. There is no explanation for the belatedness of the filing of the opposition and no request to consider the opposition notwithstanding its belatedness. Accordingly, we are not placed in a position to consider the opposition and therefore the arguments made therein have not been considered in reaching our decision to grant Bollag's Motion to Strike.

We now return to the question of whether the APJs correctly determined that Evans earlier-filed '980 application failed to provide written descriptive support and enablement for the subject matter of Counts 1 and 2 and, thus, Evans earlier-filed '980

application does not establish a constructive reduction to practice of the inventions of the counts.

1. Written Description

The APJs have held that “Bollag [i.e., Bollag Preliminary Motion 1 filed under 37 CFR §1.633(g) attacking the benefit of the December 18, 1991 filing date of Evans’ earlier-filed ‘980 application accorded Evans in the Notice declaring the interference, Paper No. 13] has satisfied the burden of proof to show that Evans’ ‘980 application fails to provide an adequate written description of the subject matter of the counts, especially with respect to treating precancerous epithelial lesions or tumors of epithelial origin and with an effective amount of 9-cis-retinoic acid,” Decision on Motions, p. 19.

Evans (EB 108) disagrees contending that the ‘980 application does provide an adequate written description of

- a. “the treatment of ‘precancerous epithelial lesions’ and ‘tumors of epithelial origin’” (EB 109-121); and,
- b. “what constitutes an effective mount of 9cisRA” (EB 121-125).

1. a. The treatment of ‘precancerous epithelial lesions’ and ‘tumors of epithelial origin’.

Regarding “the treatment of ‘precancerous epithelial lesions’ and ‘tumors of epithelial origin’,” Evans (EB 111) admits that

the ‘980 application does not disclose verbatim treating ‘precancerous epithelial lesions’ or ‘tumors of epithelial origin’ with 9cisRA,

but points out that

it discloses 'the in vivo modulation of malignant cell development, such as occurs, for example, in acute promyelocytic leukemia, testicular cancer, lung cancer, and the like' ...

The Decision on Motions (p. 14) acknowledges this.

There is ... no dispute that Evans' '980 application does not disclose verbatim "precancerous epithelial lesions" or "tumors of epithelial origin".

...

Evans' '980 application is broadly directed to treating in vivo modulation and includes treating the in vivo modulation of malignant cell development. The most specific treatments disclosed in Evans' '980 application (p. 11) are treating in vivo modulation of "acute promyelocytic leukemia, testicular cancer, lung cancer, and the like".

Processes capable of being modulated by retinoid receptors, in accordance with the present invention, also include the in vivo modulation of lipid metabolism, in vivo modulation of skin-related processes (e.g., acne, aging, wrinkling, and the like), in vivo modulation of malignant cell development, such as occurs, for example, in acute promyelocytic leukemia, testicular cancer, lung cancer, and the like.

Evans' '980 application, page 11.

The test for determining compliance with the written description requirement of the first paragraph of 35 U.S.C § 112 is whether the disclosure of the application as originally filed reasonably conveys to the artisan that Evans had possession at that time of the subject matter of the counts. In re Kaslow, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983). We have carefully reviewed Evans position on the matter (while being mindful not to consider the aforementioned newly raised arguments/declarations) and find that Evans has not persuasively shown that the APJs' decision to grant Bollag Motion 1 was in error.

We find that the APJs properly applied this test in reaching its decision and that their decision was the correct one.



The APJs found that the sole disclosure in the '980 application germane to the issue of compliance with the written description requirement is the aforementioned quote ["in vivo modulation of malignant cell development, such as occurs, for example, in acute promyelocytic leukemia, testicular cancer, lung cancer, and the like"] at page 11 of the specification of Evans' '980 application. The APJs found that this quoted passage was insufficient to reasonably convey to one of ordinary skill in the art that Evans was in possession of treating, specifically, "precancerous epithelial lesions" or "tumors of epithelial origin" as set forth in the counts. According to the APJs (p. 17 of the Decision on Motions), "[t]here [were] no blazemarks reflecting an interest on the part of Evans for treating [epithelial] lung or testicular cancers or any other cancer of epithelial origin." Thus, the APJs determined that Evans' '980 application failed to provide an adequate written description of the treatment of "precancerous epithelial lesions" or "tumors of epithelial origin" as described by the counts.

Evans' brief makes the following arguments

- (1) "the '980 application conveys possession by Evans of the subgenus of modulating malignant cell development of epithelial cancers" (EB 112-116);"
- (2) "the recent Singh decision [Singh v. Brake, 65 USPQ2d 1641 (Fed. Cir. 2003)] limits Fujikawa and supports Party Evans' arguments that: (1) the '980 is a constructive reduction to practice of the counts; and (2) the '980 application conveys possession by Evans of the subgenus of modulating malignant cell development of epithelial cancers" (EB 116-117);
- (3) "the expert testimony of record establishes that disclosure of the genus of modulating malignant cell development reasonably conveys to one of skill in the art that Party Evans had possession of the subgenus of modulating malignant cell development of epithelial cancers" (EB 117-120);

- (4) “the ‘980 applications’ written description of members within the sub-genus ‘epithelial cancers’ is sufficient to support a constructive reduction to practice of a generic count” (EB 120-121).

Evans’ argument (1), supra, is not persuasive of error in the decision.

Among the points Evans makes in support of its argument (1) are that

- “the vast majority of malignant cell development, including malignant cell development of the testes and the lung, is epithelial in nature” (EB 111);
- “the genus ‘malignant cell development’ is divided into subgenera based on the tissue of origin, there are only four subgenera owing to the fact that there are only four types of tissues in the human body (epithelial, muscle, nervous, and connective tissues) from which malignant cells can arise. Moreover, of these four subgenera, the skilled artisan knows that cancers from epithelial tissues (*i.e.*, carcinomas) represent an estimated 90% of all human cancers. This knowledge provides the skilled artisan with the necessary blazemark for epithelial. As such, the ‘980 applications’ disclosure of ‘methods of modulating malignant cell development’ reasonably conveys to the skilled artisan ‘methods of modulating malignant cell development of epithelial cancers’ (EB 112);
- “the Fujikawa [Fujikawa v. Wattanasin, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996)] and Ruschig [In re Ruschig, 379 F.2d 990, 994-95, 154 USPQ 118, 122 (CCPA 1967)] cases [which were cited in the Decision on Motions] are not applicable to situations where the genus embraces at most four species, as is the case here. An explicit blazemark is necessary when the skilled artisan needs to be directed to a single species or sub-genus of a much larger genus, but not when the genus includes only four species or subgenera” (EB 113);
- “[a]n explicit blazemark directing the skilled artisan to the ‘epithelial’ sub-genus is not needed when the genus includes only three additional members” (EB 114); and,
- “[o]ne skilled in treating malignant cell development is directed to the sub-genus of treating epithelial tumors by her knowledge of tissues and of malignant cell development. One of such skill knows that there are only four types of tissues in the human body (epithelial, muscle, nervous, and connective tissue) and that malignant cells typically arise from only two of these tissues, the epithelial and connective tissues. The knowledge that malignant cells can only possibly arise from four tissues and typically only from two, one of which is epithelial, is sufficient guidance for the artisan seeking to treat malignant cells to specifically treat tumors of epithelial origin” (EB 114-115).

We have carefully considered these points. However, we do not find Evans' argument (1) persuasive of error in the decision. We fail to see how any of the points (supra) raised in support of that argument demonstrates that "the '980 application conveys possession by Evans of the subgenus of modulating malignant cell development of epithelial cancers."

We note that Evans stresses that "the vast majority of malignant cell development, including malignant cell development of the testes and the lung, is epithelial in nature" (EB 111). That particular point - that the vast majority of malignant cell development is epithelial in nature - was not raised in the opposition to Bollag's Motion. Accordingly, the APJs were not in error for not addressing this point when making the decision to grant Bollag Motion 1. The same can be said about the point above that one of skill knows that there are only four types of tissues in the human body (epithelial, muscle, nervous, and connective tissue) and that malignant cells typically arise from only two of these tissues, the epithelial and connective tissues. The same can also be said about Evans' argument that the skilled artisan knows that 90% of all cancers come from epithelial tissues. This knowledge was not raised in the opposition. Accordingly, the APJs were not in error for not addressing this point when making the decision to grant Bollag Motion 1. Furthermore, we can find no evidence supporting the point raised in Evans' brief (p. 112) that "the skilled artisan knows that cancers from epithelial tissues ... represent an estimated 90% of all human cancers." Accordingly, we view this as nonprobative attorney argument.

We also point out that the '980 application nowhere discloses that the vast majority of malignant cell development is epithelial in nature. Accordingly, the '980 application does not convey possession by Evans of modulating malignant cell development of epithelial cancers as Evans now argues it does. There is nothing in the application which would lead one of skill to that conclusion. As has already been stated, and which is not in dispute, the only disclosure germane to the issue of whether the '980 application provides written descriptive support for "the treatment of 'precancerous epithelial lesions' and 'tumors of epithelial origin'" as set forth in the count is the following passage on page 11:

Processes capable of being modulated by retinoid receptors, in accordance with the present invention, also include the in vivo modulation of lipid metabolism, in vivo modulation of skin-related processes (e.g., acne, aging, wrinkling, and the like), in vivo modulation of malignant cell development, such as occurs, for example, in acute promyelocytic leukemia, testicular cancer, lung cancer, and the like.

Nowhere in this passage does it say that the vast majority of malignant cell development is epithelial in nature. In fact, as the record clearly establishes, acute promyelocytic leukemia, which is specifically mentioned as one of three examples of malignant cell development, is not epithelial in nature at all. The '980 application makes no distinction between cancer types. The clear impression given by the passage above is that the '980 application is directed to all types of cancer. This passage does not convey an interest on the part of Evans to treat epithelial cancers.

Furthermore, we are of the view that a generic disclosure of malignant cell development, as in the '980 application, is a disclosure of a "forest" of cancers.

Fujikawa v. Wattanasin, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905<sup>8</sup> (Fed. Cir. 1996)

tells us that where a “forest” of compounds is disclosed, a blazemark must be present to lead one to a claimed species in order for us to conclude that the specification provides written descriptive support for the claimed species. We disagree with Evans that an explicit blazemark is not needed. We agree with the APJs below that the ‘980 application must provide a blazemark.

In determining whether the ‘980 application reasonably conveys to the artisan that Evans had possession of the subject matter of the counts – which require treating epithelial cancers – the APJs looked for blazemarks leading one from the stated genus “malignant cell development” to the counts’ specific epithelial cancers. The APJs recognized that the passage mentions acute promyelocytic leukemia, testicular cancer, and lung cancer as examples of the types of malignant cell development that Evans sought to treat. However, the APJs were not persuaded that these examples provided sufficient blazemarks conveying to the artisan that Evans had possession of treating epithelial cancer as the counts require. We agree. As we stated above acute

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<sup>8</sup> “Many years ago our predecessor court graphically articulated this standard by analogizing a genus and its constituent species to a forest and its trees. As the court explained:

It is an old custom in the woods to mark trails by making blaze marks on the trees. It is no help in finding a trail ... to be confronted simply by a large number of unmarked trees. Appellants are pointing to trees. We are looking for blaze marks which single out particular trees. We see none.

In re Ruschig, 379 F.2d 990, 994-95, 154 USPQ 118, 122 (CCPA 1967).

In finding that Wattanasin’s disclosure failed to sufficiently describe the proposed sub-genus, the Board again recognized that the compounds of the proposed count were not Wattanasin’s preferred, and that his application contained no blazemarks as to what compounds, other than those disclosed as preferred, might be of special interest. In the absence of such blazemarks, simply describing a large genus of compounds is not sufficient to satisfy the written description requirement as to particular species or sub-genuses. See, e.g., id. at 994, 154 USPQ at 122. (“Specific claims to single compounds require reasonably specific supporting disclosure and while ... naming [each species] is not essential, something more than the disclosure of a class of 1000, or 100, or even 48 compounds is required.”).

promyelocytic leukemia is not epithelial in nature and the other exemplified cancers, testicular cancer and lung cancer, may or may not be epithelial in nature. Where there is not one example directed to epithelial cancer, it cannot be said that a clear blazemark exists conveying to the artisan that Evans had possession of treating epithelial cancer as the counts require.

Evans' argument (2), supra, is also not persuasive of error in the decision.

Among the points Evans makes in support of its argument (2) is that

- “[t]he Singh decision not only supports Party Evans' request that it be awarded the benefit of priority of the '980 application, it also supports a finding that the '980 application was a constructive reduction to practice of the subject matter of the counts in this interference. Because here, as in Singh, there is a limited number of relevant subgenera (Singh = 2; Evans = 4) the disclosure in the Evans '980 application of the genus of modulating malignant cell development reasonably conveys to one of skill in the art that Party Evans had possession of the subgenus of modulating malignant cell development of epithelial cancers” (EB 117);

We have carefully considered this point. However, we do not find Evans' argument (2) persuasive of error in the decision.

Picking up from the previous argument, Evans takes the position that no explicit blazemark is needed to establish Evans' interest in treating epithelial cancers where cancers are divided into subgenera.

In essence, Evans argues that it is a fact that cancers can be divided into four groups, epithelial being one of those groups, and because there are only four groups, the disclosure of cancer in the specification provides automatic written descriptive support for any one of those groups, including epithelial. In other words, Evans is of the view that because the '980 application teaches treating malignant cell development, in view of the fact that there are only four types of cancer, the '980 application necessarily

also conveys treating epithelial cancers – one of the four types. In light of this, Evans is of the view that the '980 specification does not need blazemarks to convey that Evans had possession of treating epithelial cancer as the counts require. Relying on a recent decision, Singh v. Brake, 317 F.3d 1334, 65 USPQ2d 1641 (Fed. Cir. 2003), Evans takes the position that where “there is a limited number of relevant subgenera (Singh = 2; Evans = 4) the disclosure in the Evans '980 application of the genus of modulating malignant cell development reasonably conveys to one of skill in the art that Party Evans had possession of the subgenus of modulating malignant cell development of epithelial cancers.” Evans' Brief, p. 117. According to Evans (EB 116), “the Court [in Singh] stated that the proposition based on Fujikawa that ‘an application disclosing a generic chemical formula must provide adequate direction to those of ordinary skill in the art to lead them to a subgenus of the proposed count’ was not applicable where ‘there are only two subgenera that are biologically relevant.’”

As we have stated, the alleged fact that cancers can be divided into four subgenera is a new issue not entitled to consideration. Regarding Singh, we note that Singh was decided after the Decision on Motions had issued and therefore the APJs did not have the Singh decision before them when Bollag Motion 1 was decided. Nevertheless, Singh is not on all fours with the facts in this case. In Singh, the court determined that only two subgenera were biologically relevant. That is not the case here. Nothing in the '980 disclosure gives any indication of what Evans considers to be the relevant cancer to be treated with 9cisRA. The Singh court found a clear “blazemark” in the claim of the subject application providing in ipso verbis support for

the n=0 subgenera of the count. There is no such in ipso verbis support for treating epithelial cancers in the '980 application.

Evans' argument (3), supra, is also not persuasive of error in the decision.

Among the points Evans makes in support of its argument (3) are that

- "Dr. Motzer's testimony ... supports that carcinomas ... are the most predominate," EB118;
- "Dr. Stein states that 'the vast majority of lung cancers and many testicular cancers are of epithelial origin,'" EB 119;
- "Because non-epithelial tumors of the lung are 'very rare,' epithelial tumors (carcinomas) of the lung are clearly the expressed interest in the '980 application," EB119; and,
- "a disclosure of treating cancers of the lung is a blazemark that signifies an interest on the part of Evans in treating tumors of epithelial origin as of the filing date of the '980 application." EB 120.

We have carefully considered these points. However, we do not find Evans' argument (3) persuasive of error in the decision.

The evidence, Dr. Motzer and Dr. Stein's testimony (Ex. 1106 and 1031, respectively), do not show that the lung and testicular cancer are epithelial cancers. Motzer and Stein have testified that lung and testicular cancer may be epithelial in nature and, according to Dr. Stein, most lung cancers are epithelial cancers. However, the question is not whether there are lung cancers that are epithelial in nature but whether the disclosure of the '980 application as originally filed reasonably conveys to the artisan that Evans had possession at that time of treating epithelial cancers as the counts require. The disclosure is directed to all cancers, epithelial or not. The issue is whether this disclosure of treating all cancers reasonably conveys to the artisan that



Evans had possession at that time of treating epithelial cancers in particular. We find that the disclosure does not reasonably convey to the artisan that Evans had possession at that time of treating epithelial cancers.

Evans' argument (4), supra, is also not persuasive of error in the decision.

Among the points Evans makes in support of its argument (4) are that

- "One of ordinary skill in the art, upon reading the '980 disclosure, would recognize that a description of treating all malignant cells in the lung and testes includes treating malignant cells and testes that are epithelial in origin." EB 120.

We have carefully considered this points. However, we do not find Evans' argument (4) persuasive of error in the decision. A similar point was made above in argument (3). Similarly, we find that the disclosure of treating all cancers does not reasonably convey to the artisan that Evans had possession at that time of treating epithelial cancers in particular.

We find that the APJs below correctly held that Bollag [i.e., Bollag Preliminary Motion 1 filed under 37 CFR § 1.633(g) attacking the benefit of the December 18, 1991 filing date of Evans' earlier-filed '980 application accorded Evans in the Notice declaring the interference, Paper No. 13] has satisfied the burden of proof to show that Evans' '980 application fails to provide an adequate written description of the subject matter of the counts, especially with respect to treating precancerous epithelial lesions or tumors of epithelial origin, and that Evans' has not persuasively established that its earlier-filed '980 application is a constructive reduction to practice of the subject matter of the counts.

1. b. What constitutes an effective amount of 9cisRA.

Given our decision supra that the APJs below have correctly held that “Bollag [i.e., Bollag Preliminary Motion 1 filed under 37 CFR § 1.633(g) attacking the benefit of the December 18, 1991 filing date of Evans’ earlier-filed ‘980 application accorded Evans in the Notice declaring the interference, Paper No. 13] has satisfied the burden of proof to show that Evans’ ‘980 application fails to provide an adequate written description of the subject matter of the counts, especially with respect to treating precancerous epithelial lesions or tumors of epithelial origin ...,” Decision on Motions, p. 19, and that this decision means we concurrently decide that Evans’ earlier-filed ‘980 application is not a constructive reduction to practice of the subject matter of the counts, we need not decide whether the APJs below have also correctly held that “Bollag ... has satisfied the burden of proof to show that Evans’ ‘980 application fails to provide an adequate written description of the subject matter of the counts [with respect to what constitutes an effective amount of 9cisRA].”

2. Enablement

Given our decision supra that the APJs below have correctly held that “Bollag [i.e., Bollag Preliminary Motion 1 filed under 37 CFR § 1.633(g) attacking the benefit of the December 18, 1991 filing date of Evans’ earlier-filed ‘980 application accorded Evans in the Notice declaring the interference, Paper No. 13] has satisfied the burden of proof to show that Evans’ ‘980 application fails to provide an adequate written description of the subject matter of the counts, especially with respect to treating precancerous epithelial lesions or tumors of epithelial origin ...,” Decision on Motions,

p. 19, and that this decision means we concurrently decide that Evans' earlier-filed '980 application is not a constructive reduction to practice of the subject matter of the counts, we need not decide whether the APJs below have also correctly held that Evans' earlier-filed '980 application fails to enable one of skill in the art to make and use the subject matter of Counts 1 and 2 without undue experimentation.

Evans has not met its burden of establishing priority by a preponderance of the evidence that it constructively reduced to practice the inventions of Counts 1 and 2 before senior party Bollag's priority date of January 22, 1992. Evans first alternative legal argument (see supra) for priority is therefore not persuasive.

## II. Evans Was First To Actually Reduce To Practice The Invention Of The Counts

Evans (EB 75) argues that it "can establish an actual reduction to practice of a method of administering an effective amount of 9cisRA to a patient for the purpose of treating precancerous epithelial lesions or tumors of epithelial origin, prior to January 22, 1992." Evans' position is discussed in its brief at pp. 75-86.

We have carefully considered Evans' argument and the discussion in support thereof but we find that Evans has failed to meet its burden of establishing an actual reduction to practice of the inventions of Counts 1 and 2 prior to January 22, 1992.

Reduction to practice is a legal question based on underlying factual determinations. Fujikawa v. Wattanasin, 93 F.3d 1559, 1564, 39 USPQ2d 1895, 1899 (Fed. Cir. 1996). Evans has the burden of establishing a prior actual reduction to practice by a preponderance of the evidence.

The test for establishing an actual reduction to practice is as follows:

In an interference proceeding, a party seeking to establish an actual reduction to practice must satisfy a two-prong test: (1) the party constructed an embodiment or performed a process that met every element of the interference count, and (2) the embodiment or process operated for its intended purpose.

Eaton v. Evans, 204 F.3d 1094, 1097, 53 USPQ2d 1696, 1698 (Fed. Cir. 2000). The first prong of the test requires a showing of both an actual preparation and a recognition of the embodiment of the count and the second prong of the test requires a showing of a recognition of a specific practical utility for that embodiment. Furthermore, an inventor's testimony must be corroborated by independent evidence in order to establish an actual reduction to practice. Knorr v. Pearson, 671 F.2d 1368, 1373, 213 USPQ 196, 200 (CCPA 1982), citing Reese v. Hurst, 661 F.2d 1222, 1225, 211 USPQ 936, 940 (CCPA 1981).

"With regard to the first prong, this Court's well-established precedent requires that the constructed embodiment ... include the precise elements recited in the count," Eaton v. Evans, *supra*. Evans urges that it has demonstrated a complete reduction to practice prior to Bollag's priority date of January 22, 1992 and directs our attention to "experiments that were performed by Dr. Zahra Parandoosh and Maureen Caton [between December 9 and 12, 1991 and January 17 and 20, 1992] who, on behalf of and at the direction if [sic, of] the inventors, observed that specific doses of 9cisRA could induce the differentiation of epithelial cell lines (F9 cells) that are in vitro models for precancerous epithelial origin." EB 75. These experiments, however, were conducted in vitro. The counts specifically require administering to or treating a patient, i.e., in vivo. Evans does not point us to any experiments whereby a patient was treated

with 9cisRA. The precise elements recited in the count were not performed.

Accordingly, the first prong of the test for establishing an actual reduction to practice has not been satisfied.

We agree with Bollag that

Evans has provided no evidence whatsoever that any amount of 9-cis-retinoic acid was 'administered' to any 'patient,' i.e. 'living person' or other relevant animal. Evans has provided no evidence that 9-cis-retinoic acid was administered to a patient having 'premalignant or precancerous epithelial lesions to retard the progression of these lesions into carcinomas' (Count 1) or to a patient with tumors of epithelial origin 'to retard the development of said tumors' (Count 2). And Evans has provided no evidence that 9-cis retinoic acid was administered in an amount effective to provide the therapeutic results called for by Count 1 and Count 2.

Bottom line, Evans has not established an actual reduction to practice of Count 1 or Count 2.

BB 24.

Substantially repeating what it said in its brief (EB 75-86), Evans (ERB 18-33) argues in rebuttal that

- A. "In Vivo Methods Can be Reduced To Practice Through In Vitro Experiments," ERB 19;
- B. "By Confirming The Efficacy Of 9cisRA In Epithelial Cells, Party Evans Had Completely Reduced To Practice The Subject Matter Of The Two Counts," ERB 23;
- C. "In Vitro Testing Of 9cisRA Is Sufficient To Reduce To Practice An In Vivo Method Of Treating Patients With 9cisRA Is Shown To Be As Effective As Other Retinoids Already Being Used To Treat Patients," ERB 26; and,
- D. "It is Undisputed From The Evidence Of Record That F9 Epithelial Carcinoma Cells Are An In Vitro Model For Precancerous Epithelial Lesions And Tumors Of Epithelial Origin," ERB 32.

Evans' rebuttal arguments have a common thread; that is, that the experiments Dr. Zahra Parandoosh and Maureen Caton performed on F9 cells, which are mouse teratocarcinoma cells (see p. 11, line 22 to p. 12, line 28 of Evans' involved application 07/244,857), albeit in vitro experiments, are models for in vivo treatments and, as such,

are sufficient evidence of an actual reduction to practice of treating patients with precancerous epithelial lesions and tumors of epithelial origin as set forth in the counts.

Evans provides no authority, nor are we aware of any, that holds that an in vitro experiment on animal cells is per se evidence of an actual reduction to practice of an in vivo method of treating a patient. See Fujikawa v. Wattanasin, 93 F.3d 159, 39 USPQ2d 1895 (Fed. Cir. 1996) (“in vitro testing of cells is insufficient as a matter of law to prove an actual reduction to practice of an in vivo method of treating patients”).

Even if we assumed arguendo that one could establish an actual reduction to practice of an in vivo method of treating a patient with evidence of an in vitro experiment on animal cells, Evans has failed to show a sufficient nexus between the experiments performed and the treatments of the counts. There is no dispute that Parandoosh and Caton did not perform the methods of the counts. No patient was ever treated. The question is whether the experiments they did perform, i.e., treating F9 mouse cells, are sufficient evidence that Evans actually reduced to practice the methods of the count. In our view they are not.

The correlation between the Parandoosh and Caton in vitro experiments and the methods of the counts is unclear. Evans stresses that the experiments were used as a “model for cancer” (see EB 76-77) but does not explain how these in vitro experiments using F9 mouse cells correlate with retarding the progression of premalignant or precancerous epithelial lesions into carcinomas (Count 1) and the development of tumors of epithelial origin (Count 2) in patients as the counts require. Evans (EB 76-77) argues that the results of the experiments “strongly correlates with its [i.e., 9cisRA]

ability to treat cancer in a human patient” (see also Evans Exh. 1096, Evans Declaration at 95 and Evans Exh. 100, Manglesdorf Decl. at 10) but does not explain the strength of that correlation or how that strength translates into knowledge of how the cancer will react due to the treatment. Evans directs our attention to the Heymann Declaration (Evans Exh. 1097) which states that “because 9cisRA was able to induce differentiation of the epithelial cell line F9, 9cisRA was capable of modulating proliferative cell disorders, such as cancer, occurring in epithelial tissues in patients” (at 117) and the “results confirmed ... that 9cisRA ... was an appropriate compound for treating patients with premalignant or precancerous epithelial lesions or tumors of epithelial origin if administered to patients in an effective amount” (at 128). Evans also directs our attention to the Kurie Declaration (Evans Exh. 1096) which makes similar statements. These statements merely reflect Evans’ belief that, based on the experiments, 9cisRA could be an appropriate compound for and capable of treating epithelial cancer in patients. We do not see from this, however, that Evans has shown that the experiments it conducted and the treatments of the counts are so closely related that one can reasonably conclude that Evans’ in vitro experiments amount to an actual reduction to practice of the in vivo treatments of the counts. In our view, the experiments highlight the potential efficacy and utility of 9cisRA but are insufficient evidence that Evans actually treated a patient’s epithelial cancer cells.

Regarding rebuttal argument B., although Evans agrees with Bollag that Fujikawa v. Wattanasin, 93 F.3d 159, 39 USPQ2d 1895 (Fed. Cir. 1996) holds that “in vitro testing of cells is insufficient as a matter of law to prove an actual reduction to

practice of an in vivo method of treating patients" (see ERB 23), Evans nevertheless contends that it "had already reduced to practice all the remaining limitations of the two counts vis-à-vis its prior constructive reduction to practice of a method of modulating malignant cell development, in a patient, by administering 9cisRA," ERB 24. In other words, Evans is arguing that an actual reduction to practice has been established in view of its constructive reduction to practice. However, we have already determined that Evans has failed to meet its burden of establishing a constructive reduction to practice of the subject matter of the counts.

Regarding rebuttal argument C., Evans takes the position that the evidence of record demonstrates "that 9cisRA exhibits activity, in vitro, comparable to that of other retinoids, such as 11cisRA, 13cisRA and ATRA," ERB27. However, the issue is not whether Evans has established a utility for 9cisRA but whether Evans has actually treated a patient with 9cisRA. There is no evidence that ever occurred.

Regarding rebuttal argument D., Evans argues that "F9 epithelial carcinoma cells are embryonal carcinoma cells and that 9cisRA's ability to modulate the proliferation of and differentiation of these cells strongly correlates with 9cisRA's ability to modulate the proliferation and differentiation of epithelial cells in human patients," ERB 32. Evans argues that it treated F9 epithelial cells, which are mouse teratocarcinoma cells (see p. 11, line 22 to p. 12, line 28 of Evans' involved application 07/244,857), which represents an in vitro model for the in vivo treatment of human epithelial cells, and that that establishes an actual reduction to practice of the in vivo treatment described by the counts. We disagree for the same reasons we gave above regarding the lack of



evidence of a nexus between in vitro experiments and in vivo treatments. Evans makes the argument that F9 epithelial cells are used as a model but no objective evidence has been submitted showing that conducting an experiment using this model necessarily means one has actually treated epithelial cells of a patient in vivo.

Evans has not met its burden of establishing priority by a preponderance of the evidence that it actually reduced to practice the inventions of Counts 1 and 2 before senior party Bollag's priority date of January 22, 1992. Evans second alternative legal argument (see supra) for priority is therefore not persuasive.

III. Evans Conceived Of The Invention Of The Counts Prior To January 22, 1992, And Proceeded With Diligence Toward A Constructive Reduction To Practice

As we understand it, Evans is seeking to establish that it was first to conceive the inventions of the counts and proceeded with reasonable diligence from a time just prior to Bollag entering the field toward a reduction to practice. If a preponderance of the evidence were to support it, Evans will have established priority. See Haskell v. Colebourne, 671 F.2d 1362, 1365, 213 USPQ 192, 194 (CCPA 1982). However, that has not been done. Evans has not satisfied its burden of establishing prior conception.

Evans' argument on conception begins on page 52 of its opening brief.

Conception is said to be demonstrated by

- the disclosure of Evans' '980 application;
- the inventors' awareness of the role retinoids play in treating epithelial tissue disorders; and,
- the inventors' awareness of an effective amount of 9cisRA for treatment.

Proof of Evans' conception is said to come first from Evans' '980 application (EB 5). Evans, relying on statements made in the Decision on Motions, states that the Board agreed that the '980 application discloses a method of providing 9cisRA to a living person for modulating a process mediated by retinoid receptors. EB 56. However, this alone gives no insight into whether the inventors conceived of the inventions of the count – both of which require treating epithelial-based tumors and precancerous lesions. The fact that the disclosure of the '980 application leads one to the conclusion that the inventors conceived of modulating processes mediated by retinoid receptors at the time the application was filed does not mean the inventors also conceived of treating epithelial-based tumors and precancerous lesions.

Evans then directs us to the inventors' awareness of the role retinoids play in treating epithelial tissue disorders – presumably as a way of overcoming the lack of disclosure in the '980 application to treating epithelial-based tumors and precancerous lesions. That awareness is said to be shown by the testimony of non-inventor Dr. Kurie. EB 57. However, our review of the Kurie's declaration does not indicate that the inventors had that awareness. Kurie states that "it is my opinion that, by the filing date of the '980 application, the above named inventors knew that 9cisRA could be used to treat patients having premalignant or precancerous epithelial lesions ..." See Evans Exh. 1098, p. 4. Dr. Kurie does not in fact know. It is merely his opinion that the inventors might know of the role retinoids play in treating epithelial tissue disorders. In other places in his declaration, i.e., at 83 of Evans Exh. 1098, Kurie notes experiments conducted by various individuals involving treating melanoma with 9cisRA but these

experiments were conducted well after the filing date of Evans' '980 application. Dr. Kurie's testimony does not add anything to the question of whether the inventors conceived of the inventions of the counts at the time the '980 application was filed.

Finally, Evans directs us to the Evans (Ex. 1096, 83-89); Manglesdorf (Ex. 1100, 89-95); and Heyman (Ex. 1097, 71-77) declarations in support of the position that the inventors knew that retinoids were involved in malignant epithelial tissue development and of an effective amount of 9cisRA for treatment. The Manglesdorf declaration (Ex. 1100, 90 and 94) for one does indeed state that and further states that Manglesdorf, an inventor, knew by at least the December 18, 1991 filing date that 9cisRA could be used to treat patients with epithelial-based tumors and precancerous lesions as described by the counts. However, Evans has failed to provide evidence of corroboration of any alleged conception. Price v. Symsek, 988 F.2d 1187, 26 USPQ2d 1031 (Fed. Cir. 1993). In that regard, we are directed back to Kurie's declaration which, as we alluded to above, does not evidence a contemporaneous disclosure by the inventors to Kurie that would enable one skilled in the art to make the inventions of the counts. Coleman v. Dines, 754 F.2d 353, 359, 224 USPQ 857, 862 (Fed. Cir. 1985).

We find, therefore, that Evans has not satisfied its burden of establishing prior conception. Because conception has not been established, Evans has not established priority based on the legal theory that it first conceived of the invention of the counts and proceeded with reasonable diligence to reduction to practice. The question of whether Evans established reasonable diligence is a moot question. Accordingly, Evans' third alternative legal argument (see supra) for priority is found not to be

persuasive.

We have addressed all of Evans' arguments for priority and find them unpersuasive. We determine that Evans, the junior party, has not met its burden of establishing priority by a preponderance of the evidence.

#### JUDGMENT

All the issues having been addressed, we now enter judgment in this interference pursuant to our authority under 37 CFR § 1.658(a). Accordingly, we hold the following:

Judgment as to the subject matter of both of the counts in issue is hereby awarded to Bollag et al., the senior party.

Accordingly, Werner Bollag, Joseph Francis Grippo, and Arthur Levin, the senior party, are entitled to their patent, U.S. Patent No. 5,428,071, containing claims 1-6 corresponding to Count 1 and claims 7-13 corresponding to Count 2.

Marc L. Caroff

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HUBERT C. LORIN

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Administrative Patent Judge

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